director of the division that is responsible for review of the IND. The order identifies the studies under the IND to which the hold applies and explains the basis for the action. The hold order may be made by telephone or other means of rapid communication, or in writing. Within 30 days of the imposition of the clinical hold, the division director provides the sponsor with a written explanation of the basis for the hold. Any sponsor who has not received a written explanation within 30 days should notify the division and request that it be issued. In addition to providing a statement of reasons, this ensures that the hold is recorded in CDER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit the resumption, an investigation may resume only after the division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, a sponsor may request a meeting with the review staff and management to discuss the hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center's practices in imposing clinical holds. First, CDER completed a centerwide review of clinical holds recorded in the management information system. While some differences in practice and procedure were discerned among divisions, it appeared that the procedures specified in the regulations were, in general, being followed, and that holds were scientifically supportable.

Second, FDA established a committee in CDER to review selected clinical holds for scientific and procedural quality. The committee held pilot meetings in 1991 and 1992. The trial phase of the committee review process confirmed the agency's view that the divisions in CDER impose clinical holds in a manner that is generally consistent with FDA's procedural requirements and that holds are imposed on scientifically supportable grounds.

The clinical hold committee review process is now a regular, ongoing program. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending hold to have that hold considered ''anonymously.'' The committee consists of senior managers in CDER, a senior official from the Center for Biologics Evaluation and Research, and the FDA Chief Mediator and Ombudsman. The committee now meets semiannually. The committee last met in June 1995.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review holds proposed for review by drug sponsors. In general, a drug sponsor should consider requesting review when it disagrees with the agency's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CDER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CDER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, will be available from the FDA Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new drug trial that was placed on clinical hold during the past 12 months that they want the committee to review at its October meeting. Submissions should be made by September 22, 1995 to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: August 15, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–20812 Filed 8–22–95; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the month of September 1995.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 13, 9:00 am–5:00 pm.

Place: Parklawn Building, Conference Room D, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

Agenda

Agenda items will include, but not be limited to: a report on the National Vaccine Program; a report on the Task Force for Safer Childhood Vaccines and Acellular Pertussis Vaccine Trials from the National Institutes of Health; Review of the American Academy of Pediatrics/Advisory Committee on Immunization Practices Polio and Pertussis Vaccine Recommendations; and routine Program reports.

Public comment will be permitted before noon and at the end of the Commission meeting, as time permits. Oral presentations will be limited to 5 minutes per public speaker.

Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to Mr. Jerry Anderson, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–35, 5600 Fishers Lane, Rockville, MD 20852; Telephone (301) 443–1533.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for presentation,

but desire to make an oral statement, may sign up in Conference Room D before 10:00 a.m. on September 13. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Mr. Anderson, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–35, 5600 Fishers Lane, Rockville, Maryland 20852; Telephone (301) 443–1533.

Name: National Advisory Committee on Rural Health.

Date and Time: September 17–20, 1995; 3:00 p.m.

Place: The Historic Inns of Annapolis, 16 Church Circle, Annapolis, MD 21401, (410) 263–2641.

The meeting is open to the public.

Agenda

The meeting will begin on Sunday, September 17, with an orientation for the four new members that were appointed. The orientation session will cover the purpose of the Committee, the structure of the meetings, a description of the Office of Rural Health Policy, introduction to TASCON (the Committee's logistics contractor), and a discussion of the Committee's accomplishments to date. A presentation on Conflict of Interest and Ethics will be presented.

The Plenary Session will begin at 8 a.m. on Monday, September 18. This meeting will be devoted to developing directions for a national rural health agenda and strategic planning for the future.

Anyone requiring information regarding the subject Committee should contact Dena S. Puskin, Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Ms. Arlene Granderson, Office of Rural Health Policy, Health Resources and Services Administration, Telephone (301) 443–0835.

Name: National Advisory Council on Nurse Education and Practice and Council on Graduate Medical Education.

Date and Time: September 27, 1995, 8:30 a.m.–11:30 a.m.

Place: Bethesda Marriott, Salon A–B of the Grand Ballroom, 5151 Pooks Hill Road, Bethesda, Maryland 20814.

The meeting is open to the public.

Agenda

Agenda items on which the councils will make recommendations are the computer-based requirements model developed by the contractor and the requirements projections. Membership will also provide recommendations to the Director, Bureau of Health Professions based on the model and. The council will also review the work done in small groups and recommend future work that may be needed.

Anyone wishing to obtain a roster of members, or an agenda for the meeting contact R. Margaret Truax at (301) 443–5786.

Name: National Advisory Council on Nurse Education and Practice.

Date and Time: September 27, 1995, 1:30 p.m.–4:30 p.m.;

Place: Bethesda Marriott, Salon A–B of the Grand Ballroom, 5151 Pooks Hill Road, Bethesda, Maryland 20814.

The meeting is open to the public.

Agenda

Agenda items for the meeting will cover announcements, review of the computer based requirements model developed by a contractor and recommendations of the Council on Graduate Medical Education and the National Advisory Council on Nurse Education and Practice workgroups.

Anyone wishing to obtain a roster of members, minutes of meeting or other relevant information should write or contact Ms. Melanie Timberlake, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9–36, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301)443–5786.

Name: Council on Graduate Medical Education.

Date and Time: September 27, 1995, 3:00 p.m.–5:00 p.m.; September 28, 1995, 8:30 a.m.–3:00 p.m.

Place: Holiday Inn, Capitol, 550 C Street, SW., Washington, DC 20024.

This meeting is open to the public.

Agenda

The agenda will include a panel to discuss future directions for Graduate Medical Education in a managed care world; a panel to discuss a COGME retrospective and vision for the future; an update on COGME activities and a discussion of Fiscal Year 1996 activities.

Anyone requiring information regarding the subject should contact F. Lawrence Clare, M.D., M.P.H., Acting Executive Secretary, telephone (301) 443–6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Health Resources and Service Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Dated: August 17, 1995.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 95–20814 Filed 8–22–95; 8:45 am]

BILLING CODE 4160–15–P

Public Health Services

National Institutes of Health (NIH); Notice of the Meeting of the National Advisory Eye Council

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Eye Council (NAEC) on September 15, 1995, Executive Plaza North, Conference Room H, 6130 Executive Boulevard, Bethesda, Maryland.

The NAEC meeting will be open to the public on September 15 from 8:30 a.m. until approximately 11:30 a.m. Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs and policies. Attendance by the public at the open session will be limited to space available.

In accordance with provisions set forth in Secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and Sec. 10(d) of Public Law 92–463, the meeting of the NAEC will be closed to the public on September 15 from approximately 11:30 a.m. until adjournment at approximately 5:00 p.m. for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Lois DeNinno, Committee Management Officer, National Eye Institute, EPS, Suite 350, 6120 Executive Boulevard, MSC–7164, Bethesda, Maryland 20892–7164, (301) 496–5301, will provide a summary of the meeting, roster of committee members, and substantive program information upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. DeNinno in advance of the meeting.